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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,447	01/10/2001	Leigh T Canham	124-822	2227

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EXAMINER

BEISNER, WILLIAM H

ART UNIT

PAPER NUMBER

1744

DATE MAILED: 11/25/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

AS-6

Office Action Summary

Application No.

09/743,447

Applicant(s)

CANHAM, LEIGH T

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2002 and 10 October 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 January 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

Information Disclosure Statement

1. The Examiner confirms receipt of a copy of the parent application, 09/095,221, to Patent No. 6,334,856 and a copy of the "Certificate of Correction" in Patent No. 6,234,856.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-10 and 16-28 rejected under 35 U.S.C. 102(e) as being anticipated by Allen et al.(US 6,334,856).

The reference of Allen et al. discloses a device and method of use for transferring of material into cells. The reference discloses the use of an array of microneedles which are made of porous silicon (See column 10, lines 4-18 and column 11, lines 15-46). The reference also discloses that the porous material can also be made hollow (See column 5, lines 7-26).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 11, 14, 15, 29, 30 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen et al.(US 6,334,856) in view of Trimmer et al.(WO 96/10630).

The reference of Allen et al. has been discussed above.

Claims 11, 29 and 30 above differ by reciting that the porous silicon is in the form of a bullet.

The reference of Trimmer et al. discloses microneedle array device which discloses an embodiment which employs barbed needles (42 of Fig. 4) wherein the barb (42") break off once inserted into the cell. This structure meets the claim language of a "bullet" carrier.

In view of this teaching, it would have been obvious to one of ordinary skill in the art to modify the structure of the array of the primary reference to include the structure disclosed by the reference of Trimmer et al. for the known and expected advantages associated with the barbed structure.

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Claims 14, 15 and 32 differ by reciting that the microneedles are electrodes for using electroporosis to convey the substance into the cell.

The reference of Trimmer et al. discloses that it is known in the art to increase the uptake of substance when using microneedles by applying electrical pulses to the microneedles (See page 13, lines 15-34).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the microneedles of the primary reference as microelectrodes for the known and expected result of increasing the uptake of material which can be provided by electrical pulses when the microneedles are contacted with the cells.

6. Claim 12, 13 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen et al.(US 6,334,856) in view of Wurm et al.(US 5,484,720).

The reference of Allen et al. has been discussed above.

The above claims differ by reciting that the carrier substance co-precipitates with calcium phosphate.

The reference of Wurm et al. discloses that it is known in the art to provide nucleic acid particles for transfection by using a co-precipitate of calcium phosphate (See the entire disclosure).

In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to employ calcium phosphate with the carrier material of the primary reference for the known and expected result of

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co-precipitation of the nucleic acid material with respect to the porous silicon carrier material which is an art recognize manner in which to prepare nucleic acid prior to introduction into cells.

Response to Arguments

2. Applicant's arguments filed 23 Sept. 2002 have been fully considered but they are not persuasive.

Applicant argues that the prior art rejection of record over the reference of Allen et al.(US 6,334,856) is improper for the following reasons:

i) The reference of Allen et al. (US 6,334,856) has a U.S. filing date of 21 May 1999 while the instant application has benefit of a U.K. priority document dated 22 July 1998.

ii) The parent application, 09/095,221, of U.S. Patent 6,334,856 is not available as prior art against the instant claims because this application was never issued and as a result is not a printed publication.

Applicant's comments are not persuasive for the following reasons:

i) While applicant may have benefit of the foreign priority date of 22 July 1998, the effective filing date of the Allen et al. patent (US 6,334,856) is 10 June 1998 in view of the claim under 35 USC 120 to parent application 09/095,221 which was filed on 10 June 1998. The subject matter relied upon in the disclosure of the Allen et al. patent (US 6,334,856) is also supported by the disclosure of the parent application 09/095,221 (See page 6, line 20 to page 7, line 10; page 12, lines 1-12; and page 14, lines 3-21). See M.P.E.P. 2136.03 parts III and IV.

ii) Parent application 09/095,221 was not being relied upon as a printed publication. The reference which is being applied as prior art is U.S. Patent 6,334,856 applied under 35 USC

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102(e). This patent has an effective filing date of 10 June 1998 in view of a claim under 35 USC 120 to parent application 09/095,221 and because the subject matter used to make the rejection is supported by the disclosure of application 09/095,221.

Conclusion

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 703-308-4006. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:40am to 4:10pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Warden can be reached on 703-308-2920. The fax phone numbers for the

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organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



William H. Beisner
Primary Examiner
Art Unit 1744

WHB

November 22, 2002